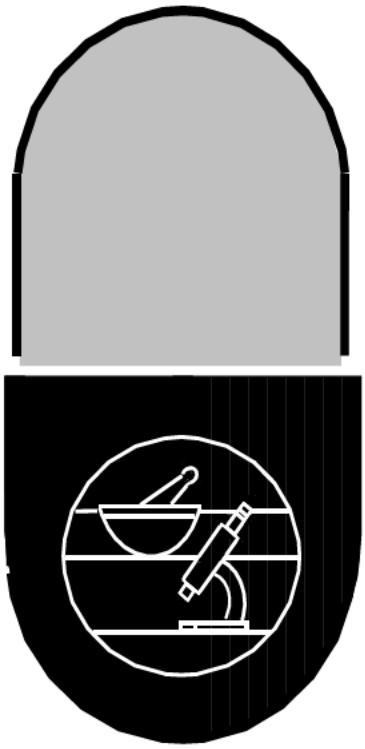
Exhibit 7



APPROVED DRUG PRODUCTS

WITH

THERAPEUTIC EQUIVALENCE EVALUATIONS

38th EDITION

THE PRODUCTS IN THIS LIST HAVE BEEN APPROVED UNDER SECTION 505 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF GENERIC DRUGS
OFFICE OF GENERIC DRUG POLICY

2018

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

The products in this list have been approved under section 505 of the Federal Food, Drug, and Cosmetic Act. This volume is current through December 31, 2017.

38th EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF GENERIC DRUGS
OFFICE OF GENERIC DRUG POLICY

2018

FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVED DRUG PRODUCTS
With
Therapeutic Equivalence Evaluations

CONTENTS

PAGE

FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVED DRUG PRODUCTS
With
Therapeutic Equivalence Evaluations

PREFACE TO THIRTY EIGHTH EDITION

The publication, *Approved Drug Products With Therapeutic Equivalence Evaluations* (the List, commonly known as the Orange Book), identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The main criterion for the inclusion of any product is that the product is the subject of an application with an approval that has not been withdrawn for safety or efficacy reasons. Inclusion of products in the Orange Book is independent of any current regulatory action through administrative or judicial means against a drug product. In addition, the Orange Book contains therapeutic equivalence evaluations for approved multisource prescription drug products. These evaluations have been prepared to serve as public information and advice to state health agencies, prescribers, and pharmacists to promote public education in the area of drug product selection and to foster containment of health care costs. Therapeutic equivalence evaluations in this publication are not official FDA actions affecting the legal status of products under the FD&C Act.

Background of the Publication. To contain drug costs, virtually every state has adopted laws and/or regulations that encourage the substitution of drug products. These state laws generally require either that substitution be limited to drugs on a specific list (the positive formulary approach) or that it be permitted for all drugs except those prohibited by a particular list (the negative formulary approach). Because of the number of requests in the late 1970s for FDA assistance in preparing both positive and negative formularies, it became apparent that FDA could not serve the needs of each state on an individual basis. The Agency also recognized that providing a single list based on common criteria would be preferable to evaluating drug products on the basis of differing definitions and criteria in various state laws. As a result, on May 31, 1978, the Commissioner of the Food and Drug Administration sent a letter to officials of each state announcing FDA's intent to provide a list of all prescription drug products that are approved by FDA for safety and effectiveness, along with therapeutic equivalence determinations for multisource prescription products.

The Orange Book was distributed as a proposal in January l979. It included only currently marketed prescription drug products approved by FDA through new drug applications (NDAs) and abbreviated new drug applications (ANDAs) under the provisions of Section 505 of the FD&C Act.

The therapeutic equivalence evaluations in the Orange Book reflect FDA's application of specific criteria to the multisource prescription drug products listed in the Orange Book and approved under Section 505 of the FD&C Act. These evaluations are presented in the form of code letters that indicate the basis for the evaluation made. An explanation of the codes appears in the *Introduction*.

A complete discussion of the background and basis of FDA's therapeutic equivalence evaluation policy was published in the *Federal Register* on January 12, 1979 (44 FR 2932). The final rule, which includes FDA's responses to the public comments on the proposal, was published in the *Federal Register* on October 31, 1980 (45 FR 72582). The first publication of the Orange Book in October 1980, concurrent with finalization of the rule, incorporated appropriate corrections and additions. Each subsequent edition has included new approvals and made appropriate changes in data.

On September 24, 1984, the President signed into law the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments). The Hatch-Waxman Amendments require that FDA, among other things, make publicly available a list of approved drug products with monthly supplements. The Orange Book and its monthly Cumulative Supplements satisfy this requirement. The *Addendum* to this publication identifies drugs that qualify under the FD&C Act for periods of exclusivity and provides patent information concerning the listed drugs. The *Addendum* also provides additional information that may be helpful to those submitting an NDA or ANDA to the Agency.

The Agency intends to use this publication to further its objective of obtaining input and comment on the publication itself and related Agency procedures. Therefore, if you have comments on how the publication can be improved, please send them to the Director, Division of Legal and Regulatory Support, Office of Generic Drug Policy, Office of Generic Drugs, Center for Drug Evaluation and Research, 7620 Standish Place, Rockville, MD 20855-2773. Comments received are publicly available to the extent allowable under the Freedom of Information Act and FDA regulations.

1.0 INTRODUCTION

1.1 Content and Exclusion

The Orange Book is composed of four parts: (1) approved prescription drug products with therapeutic equivalence evaluations; (2) approved over-the-counter (OTC) drug products for those drugs that may not be marketed without NDAs or ANDAs because they are not covered under existing OTC monographs; (3) drug products with approval under Section 505 of the FD&C Act administered by the Center for Biologics Evaluation and Research; and (4) a cumulative list of approved products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing and we have not determined that they were withdrawn for safety or effectiveness reasons, or have had their approvals withdrawn for other than safety or efficacy reasons subsequent to being discontinued from marketing.[1] This publication also includes indices of prescription and OTC drug products by trade name (proprietary name) or established name (if no trade name exists) and by applicant name (holder of the approved application), which have been abbreviated for this publication. Established names for active ingredients generally conform to official compendial names or *United States Adopted Names* (USAN) as described in (21 CFR 299.4(e)). A list of uniform terms is provided in Appendix C.

The *Addendum* contains patent and exclusivity information for the Prescription, OTC, Discontinued Drug Product Lists, and for the Drug Products with Approval under Section 505 of the FD&C Act Administered by the Center for Biologics Evaluation and Research. The publication may include additional information that the Agency deems appropriate to disseminate.

Prior to the 6th Edition, the publication had excluded OTC drug products and drug products with approval under Section 505 of the FD&C Act administered by the Center for Biologics Evaluation and Research. The Hatch-Waxman Amendments required the Agency to begin publishing an up-to-date list of all marketed drug products, OTC as well as prescription, that have been approved for safety and efficacy and for which new drug applications are required.

Under the FD&C Act, some drug products are given tentative approvals. The Agency will not include drug products with tentative approvals in the Orange Book because a drug product that is granted tentative approval is not an approved drug product. Tentative approval lists by month are available on FDA's website Drugs@FDA. When the tentative approval becomes a final approval through a subsequent action letter to the applicant, the Agency will list the drug product and the date of approval in the appropriate approved drug product list.

Distributors or repackagers of products listed in the Orange Book are not identified.

1.2 Therapeutic Equivalence-Related Terms

[1] Newly approved products are added to parts 1, 2, or 3, of the Orange Book, depending on the dispensing requirements (prescription or OTC) or approval authority, unless the Orange Book staff is otherwise notified before publication.

Pharmaceutical Equivalents. Drug products are considered pharmaceutical equivalents if they contain the same active ingredients, are of the same dosage form and route of administration, and are formulated to contain the same amount of active ingredient and to meet the same or compendial or other applicable standards (i.e., strength, quality, purity, and identity).[2] They may differ in characteristics such as shape, scoring configuration, release mechanisms, packaging, excipients (including colors, flavors, preservatives), expiration date/time, and, within certain limits, labeling.

Pharmaceutical Alternatives. Drug products are considered pharmaceutical alternatives if they contain the same therapeutic moiety, but are different salts, esters, or complexes of that moiety, or are different dosage forms or strengths (e.g., tetracycline hydrochloride, 250mg capsules vs. tetracycline phosphate complex, 250mg capsules; quinidine sulfate, 200mg tablets vs. quinidine sulfate, 200mg capsules).[3] Different dosage forms and strengths within a product line by a single manufacturer are thus pharmaceutical alternatives, as are extended-release products when compared with immediate-release or standard-release formulations of the same active ingredient.

Therapeutic Equivalents. Drug products are considered to be therapeutic equivalents only if they are pharmaceutical equivalents for which bioequivalence has been demonstrated, and they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.[4]

FDA classifies as therapeutically equivalent those products that meet the following general criteria: (1) they are approved as safe and effective; (2) they are pharmaceutical equivalents in that they (a) contain identical amounts of the same active drug ingredient in the same dosage form and route of administration, and (b) meet compendial or other applicable standards of strength, quality, purity, and identity; (3) they are bioequivalent in that (a) they do not present a known or potential bioequivalence problem, and they meet an acceptable *in vitro* standard, or (b) if they do present such a known or potential problem, they are shown to meet an appropriate bioequivalence standard; (4) they are adequately labeled; and (5) they are manufactured in compliance with Current Good Manufacturing Practice regulations. *The concept of therapeutic equivalence, as used to develop the Orange Book, applies only to drug products containing the same active ingredient(s) and does not encompass a comparison of different therapeutic agents used for the same condition (e.g., meperidine hydrochloride vs. morphine sulfate for the treatment of pain).* Any drug product in the Orange Book repackaged and/or distributed by other than the applicant is considered to be therapeutically equivalent to the applicant's drug product even if the applicant's drug product is single source or coded as non-equivalent (e.g., **BN**). Distributors or repackagers of an applicant's drug product are not identified in the Orange Book.

FDA considers drug products to be therapeutically equivalent if they meet the criteria outlined above, even though they may differ in certain other characteristics such as shape, scoring configuration, release mechanisms, packaging, excipients (including colors, flavors, preservatives), expiration date/time and certain aspects of labeling (e.g., the presence of specific pharmacokinetic information), and storage conditions. When such differences are important in the care of a particular patient, it may be appropriate for the prescribing physician to require that a specific product be dispensed as a medical necessity. With this limitation, however, FDA believes that

2 See generally 21 CFR 314.3(b).
3 See generally 21 CFR 314.3(b).
4 See generally 21 CFR 314.3(b).

products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product.

Strength. Strength refers to the amount of drug substance contained in, delivered, or deliverable from a drug product, which includes: (1)(a) the total quantity of drug substance in mass or units of activity in a dosage unit or container closure (*e.g.*, weight/unit dose, weight/volume or weight/weight in a container closure, or units/volume or units/weight in a container closure); and/or, as applicable, (b) the concentration of the drug substance in mass or units of activity per unit volume or mass (*e.g.*, weight/weight, weight/volume, or units/volume); or (2) such other criteria the Agency establishes for determining the amount of drug substance contained in, delivered, or deliverable from a drug product if the weights and measures described in clause (1)(a) do not apply (*e.g.*, certain drug-device combination products for which the amount of drug substance is emitted per use or unit time).[5] Note that if the criteria the Agency establishes for determining and expressing the amount of drug substance in a product evolves over time, the Agency generally does not intend to revise the expressions of strength for drug products already included in the Orange Book, but rather intends to apply the criteria prospectively to drug products added to the Orange Book.

Although the strength of drug products in the Orange Book is generally expressed in terms of the amount of drug substance (active ingredient) in the drug product, it is sometimes expressed in terms of the amount of the active moiety. For example, certain drug products included in the Orange Book include a designation of "EQ" next to their expression of strength. This "EQ" designation generally is used in connection with salt drug products to indicate that the strength of such drug product is being expressed in terms of the equivalent strength of the active moiety (e.g., "EQ 200MG BASE"), rather than in terms of the strength of the active ingredient.

Bioavailability. Bioavailability is the rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of drug action. For drug products that are not intended to be absorbed into the bloodstream, bioavailability may be assessed by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or active moiety becomes available at the site of drug action.

Bioequivalence. Bioequivalence is the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. Section 505 (j)(8)(B) of the FD&C Act describes one set of conditions under which a test and reference listed drug (see Section 1.4) shall be considered bioequivalent:

> the rate and extent of absorption of the [test] drug do not show a significant difference from the rate and extent of absorption of the [reference] drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or
>
> the extent of absorption of the [test] drug does not show a significant difference from the extent of absorption of the [reference] drug when administered at the same molar dose of the therapeutic ingredient under

5 See generally 21 CFR 314.3(b).

> similar experimental conditions in either a single dose or multiple doses and the difference from the [reference] drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

Where these above methods are not applicable (e.g., for drug products that are not intended to be absorbed into the bloodstream), other scientifically valid *in vivo* or *in vitro* test methods to demonstrate bioequivalence may be appropriate.

For example, bioequivalence may sometimes be demonstrated using an *in vitro* bioequivalence standard, especially when such an *in vitro* test has been correlated with human *in vivo* bioavailability data. In other situations, bioequivalence may sometimes be demonstrated through comparative clinical trials or pharmacodynamic studies.

1.3 Further Guidance on Bioequivalence

FDA's regulations and guidance documents provide additional information regarding bioequivalence and bioavailability, including methodologies and statistical criteria used to establish the bioequivalence of drug products.[6]

1.4 Reference Listed Drug and Reference Standard

A reference listed drug (21 CFR 314.3(b)) means the listed drug identified by FDA as the drug product upon which an applicant relies in seeking approval of its ANDA. Generally, a reference listed drug is a drug product approved in a new drug application under Section 505(c) of the FD&C Act based on full reports of investigations of safety and effectiveness. For an ANDA based on an approved suitability petition (a petitioned ANDA), the reference listed drug generally is the listed drug referenced in the approved suitability petition.[7]

A reference standard is the drug product selected by FDA that an applicant seeking approval of an ANDA must use in conducting an *in vivo* bioequivalence study required for approval. FDA generally selects a single reference standard that ANDA applicants must use in *in vivo* bioequivalence testing. Ordinarily, FDA will select the reference listed drug as the reference standard. However, in some instances (e.g., where the reference listed drug has been withdrawn from sale and FDA has determined it was not withdrawn for reasons of safety or effectiveness, and FDA selects an ANDA as the reference standard), the reference listed drug and the reference standard may be different.

---

6 We note that prior editions of the Preface to the Orange Book included a section entitled "Statistical Criteria for Bioequivalence." Please see FDA's regulations and guidance documents for additional information regarding bioequivalence and bioavailability. See FDA Drugs guidance Web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm; FDA Drugs guidance (Product-Specific Recommendations for Generic Drug Development) Web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075207.htm; see generally 21 CFR part 320.

7 21 CFR 314.94(a)(3)(i).

FDA identifies reference listed drugs in the Prescription Drug Product, OTC Drug Product, and Discontinued Drug Product Lists. Listed drugs identified as reference listed drugs represent drug products upon which an applicant can rely in seeking approval of an ANDA. FDA intends to update periodically the reference listed drugs identified in the Prescription Drug Product, OTC Drug Product, and Discontinued Drug Product Lists, as appropriate.

FDA also identifies reference standards in the Prescription Drug Product and OTC Drug Product Lists. Listed drugs identified as reference standards represent the FDA's best judgment at this time as to the appropriate comparator for purposes of conducting any *in vivo* bioequivalence studies required for approval.

In some instances when FDA has not designated a listed drug as a reference listed drug, such listed drug may be shielded from generic competition. If FDA has not designated a reference listed drug for a drug product the applicant intends to duplicate, the potential applicant may ask FDA to designate a reference listed drug for that drug product. Potential applicants should consult agency guidance related to referencing approved drug products in ANDA submissions for information on submitting such a request. Section 1.7, *Therapeutic Equivalence Evaluations Codes* (*products meeting necessary bioequivalence requirements*) explains the character coding system (e.g., ***AB, AB1, AB2, AB3***...) for multisource drug products listed under the same heading with two or more reference listed drugs.

A potential applicant should consult Agency guidance related to referencing approved drug products in ANDA submissions for information on submitting a request for selection of a reference standard. FDA may, on its own initiative, select a new reference standard when doing so will help to ensure that applications for generic drugs may be submitted and evaluated, e.g., in the event that the listed drug currently selected as the reference standard has been withdrawn from sale for other than safety and efficacy reasons.

If an applicant has a question related to the appropriate reference standard, it is recommended that an applicant planning to conduct an *in vivo* bioequivalence study submit a controlled correspondence to the Office of Generic Drugs.

1.5 General Policies and Legal Status

The Orange Book contains public information and advice. It does not mandate the drug products that are purchased, prescribed, dispensed, or substituted for one another, nor does it, conversely, mandate the products that should be avoided. To the extent that the Orange Book sets forth FDA's evaluations of the therapeutic equivalence of drug products that have been approved, it contains FDA's advice to the public, to practitioners, and to the states regarding drug product selection. These evaluations do not constitute determinations that any product is in violation of the FD&C Act or that any product is preferable to any other. Therapeutic equivalence evaluations are a scientific judgment based upon evidence, while generic substitution may involve social and economic policy administered by the states, intended to reduce the cost of drugs to consumers. To the extent that the Orange Book identifies drug products approved under Section 505 of the FD&C Act, it sets forth information that the Agency is required to publish and that the public is entitled to under the Freedom of Information Act. Exclusion of a drug product from the Orange Book does not necessarily mean that the drug product is in violation of Section 505 of the FD&C Act, that such a product is not safe or effective, or that such a product is not therapeutically equivalent to other drug products. Rather, the exclusion may

be based on the fact that FDA has not evaluated the safety, effectiveness, and quality of the drug product.

1.6 Practitioner/User Responsibilities

Professional care and judgment should be exercised in using the Orange Book. Evaluations of therapeutic equivalence for prescription drugs are based on scientific and medical evaluations by FDA. Products evaluated as therapeutically equivalent can be expected, in the judgment of FDA, to have equivalent clinical effect and no difference in their potential for adverse effects when used under the conditions of their labeling. However, these products may differ in other characteristics such as shape, scoring configuration, release mechanisms, packaging, excipients (including colors, flavors, preservatives), expiration date/time, and, in some instances, labeling. If products with such differences are substituted for each other, there is a potential for patient confusion due to differences in color or shape of tablets, inability to provide a given dose using a partial tablet if the proper scoring configuration is not available, or decreased patient acceptance of certain products because of flavor. For example, there may also be allergic reactions in rare cases due to a coloring or a preservative ingredient, as well as differences in cost to the patient.

FDA evaluation of therapeutic equivalence in no way relieves practitioners of their professional responsibilities in prescribing and dispensing such products with due care and with appropriate information to individual patients. In those circumstances where the characteristics of a specific product, other than its active ingredient, are important in the therapy of a particular patient, the physician's prescribing of that product may be appropriate. Pharmacists must also be familiar with the different characteristics of therapeutically equivalent products, e.g., expiration dates/times and labeling directions for storage of the different products (particularly for reconstituted products), so they can properly advise patients when one product is substituted for another.

Multisource and single-source drug products. In the Orange Book, FDA has evaluated for therapeutic equivalence only multisource prescription drug products approved under Section 505 of the FD&C Act, which in most instances means those pharmaceutical equivalents available from more than one manufacturer. For such products, a therapeutic equivalence code is included and product information is highlighted in bold face and underlined. Those products with approved applications that are single-source (i.e., there is only one approved product available for that active ingredient, dosage form, route of administration, and strength) are also included in the Orange Book, but no therapeutic equivalence code is included with such products. Any drug product in the Orange Book repackaged and/or distributed by other than the applicant (e.g., an authorized generic) is considered to be therapeutically equivalent to the applicant’s drug product even if the applicant’s drug product is single source or coded as non-equivalent (e.g., **BN**). The details of these codes and the policies underlying them are discussed in Section 1.7, *Therapeutic Equivalence Evaluations Codes*. Distributors or repackagers of an applicant’s drug product are not identified in the Orange Book.

Products in the Orange Book are identified by the names of the holders of approved applications (applicants) who may not necessarily be the manufacturer of the product. There are numerous entities other than the applicant that may be involved in the development, manufacturing, and/or marketing of a product. The applicant may have had its product manufactured by a contract manufacturer and may simply be distributing the product for which it has obtained approval. In many instances, however, the manufacturer of the product is also the applicant. The name of the manufacturer is

permitted by regulation to appear on the label, even when the manufacturer is not the applicant or marketer.

Although the products in the Orange Book are identified by the names of the applicants, circumstances, such as changing corporate ownership, have sometimes made identification of the applicant difficult. The Agency believes, based on continuing document review and communication with firms, that the applicant designations in the Orange Book are, in most cases, correct.

To relate firm name information on a product label to that in the Orange Book, the following should be noted: the applicant's name always appears in the Orange Book. This applies whether the applicant (firm name on the Form FDA 356h in the application) is the manufacturer or marketer (firm name in largest letters on the label) or not. However, the applicant's name may not always appear on the label of the product.

If the applicant is the marketer, its name appears in the Orange Book and on the label; if the applicant is not the marketer, and the Agency is aware of a corporate relationship (e.g., parent and subsidiary) between the applicant and the marketer, the name of the applicant appears in the Orange Book and both firm names may appear on the label. Firms with known corporate relationships are displayed in Appendix B. If there is no known corporate relationship between the applicant and the marketer, the applicant's name appears in the Orange Book; however, unless the applicant is the manufacturer, packager, or distributor, the applicant's name may not appear on the label. In this case, the practitioner, from labeling alone, will not be able to relate the marketed product to an applicant cited in the Orange Book, and hence to a specific approved drug product. In such cases, to assure that the product in question is the subject of an approved application, the firm named on the label should be contacted.

To relate trade name (proprietary name) information on a product label to that in the Orange Book, the following should be noted: if the applicant is the marketer, the applicant’s name appears in the Orange Book and on the label; if the Agency is aware of a corporate relationship between the applicant and the marketer, the trade name (proprietary name) of the drug product (established name of the active ingredient, if no trade name exists) appears in the Orange Book. If a corporate relationship exists between an applicant and a marketer and both firms are distributing the drug product, the FDA reserves the right to select the trade name of either the marketer or the applicant to appear in the Orange Book. If there is no known corporate relationship between the applicant and the marketer, the established drug name (i.e., non-proprietary name) appears in the Orange Book.

Every product in the Orange Book is subject at all times to regulatory action. From time to time, approved products may be found in violation of one or more provisions of the FD&C Act. In such circumstances, the Agency may commence appropriate enforcement action to correct the violation, if necessary, by securing removal of the product from the market by voluntary recall, seizure, or other enforcement actions. Such regulatory actions are, however, independent of the inclusion of a product in the Orange Book. The main criterion for inclusion of a product is that it has an application that has been approved and that has not been withdrawn for safety or efficacy reasons. FDA believes that retention of a violative product in the Orange Book will not have any significant adverse health consequences, because other legal mechanisms are available to the Agency to prevent the product's actual marketing. FDA may however, change a product's therapeutic equivalence rating if the circumstances giving rise to the violation change or otherwise call into question the Agency's assessment of whether a product meets the criteria for therapeutic equivalence.

1.7 Therapeutic Equivalence Evaluations Codes

Generally, drug products that the Agency considers multisource have been assigned a therapeutic equivalence code. The coding system for therapeutic equivalence evaluations is designed to allow users to determine quickly whether the Agency has evaluated a particular approved product (e.g., a particular strength of an approved drug) as therapeutically equivalent to other pharmaceutically equivalent products (first letter) and to provide additional information on the basis of FDA's evaluations (second letter). With some exceptions (e.g., therapeutic equivalence evaluations for certain 505(b)(2) applications), the therapeutic equivalence evaluation date is the same as the approval date.

The two basic categories into which multisource drugs have been placed are indicated by the first letter of the relevant therapeutic equivalence code as follows:

A Drug products that FDA considers to be <u>therapeutically equivalent</u> to other pharmaceutically equivalent products, i.e., drug products for which:

(1) there are no known or suspected bioequivalence problems. These are designated **AA**, **AN**, **AO**, **AP**, or **AT**, depending on the dosage form; or

(2) actual or potential bioequivalence problems have been resolved with adequate *in vivo* and/or *in vitro* evidence supporting bioequivalence. These are designated **AB**.

B Drug products that FDA at this time, considers <u>not to be therapeutically equivalent</u> to other pharmaceutically equivalent products, i.e.,

drug products for which actual or potential bioequivalence problems have not been resolved by adequate evidence of bioequivalence. Often the problem is with specific dosage forms rather than with the active ingredients. These are designated **BC**, **BD**, **BE**, **BN**, **BP**, **BR**, **BS**, **BT**, **BX**, or **B***.

Individual drug products have been evaluated as therapeutically equivalent to the reference product in accordance with the definitions and policies outlined below:

"A" CODES

Drug products that are considered to be therapeutically equivalent to other pharmaceutically equivalent products.

"**A**" products are those for which there are no known or suspected bioequivalence problems or for which actual or potential bioequivalence problems have been resolved with adequate *in vivo* and/or *in vitro* evidence supporting bioequivalence. Drug products designated with an "**A**" code fall under one of two main policies:

(1) for those active ingredients or dosage forms for which no *in vivo* bioequivalence issue is known or suspected, the information necessary to show bioequivalence between pharmaceutically equivalent products is either presumed and considered self-evident (based on other information in the application for some dosage forms (e.g., solutions)) or satisfied by a showing that an acceptable *in vitro* dissolution standard is met. A

therapeutically equivalent rating is assigned such products so long as they are manufactured in accordance with Current Good Manufacturing Practice regulations and meet the other requirements of their approved applications (these are designated **AA**, **AN**, **AO**, **AP**, or **AT**, depending on the dosage form, as described below); or

(2) for those Drug Efficacy Study Implementation (DESI) drug products containing active ingredients or dosage forms that have been identified by FDA as having actual or potential bioequivalence problems, and for post-1962 drug products in a dosage form presenting a potential bioequivalence problem, an evaluation of therapeutic equivalence is assigned to pharmaceutical equivalents only if the approved application contains adequate scientific evidence establishing through *in vivo* and/or *in vitro* studies the bioequivalence of the product to a selected reference product (these products are designated as **AB**).

There are some general principles that may affect the substitution of pharmaceutically equivalent products in specific cases. Prescribers and dispensers of drugs should be alert to these principles so as to deal appropriately with situations that require professional judgment and discretion.

There may be labeling differences among pharmaceutically equivalent products that require attention on the part of the health professional (e.g., pharmaceutically equivalent powders to be reconstituted for administration as oral or injectable liquids may vary with respect to their expiration time or storage conditions after reconstitution). FDA's determination that such products are therapeutically equivalent is applicable only when each product is reconstituted, stored, and used under the conditions specified in its labeling.

The Agency may use notes in this publication to point out special situations, such as potential differences between two drug products that have been evaluated as bioequivalent and otherwise therapeutically equivalent, when they should be brought to the attention of health professionals. These notes are contained in Section 1.8, *Description of Certain Special Situations*.

For example, in certain instances, there may be variations among therapeutically equivalent products in their use or in conditions of administration. Such differences may be due to patent or exclusivity rights associated with such use. When such variations may, in the Agency's opinion, affect prescribing or substitution decisions by health professionals, a note may be added to Section 1.8.

Also, occasionally a situation may arise in which changes in a listed drug product after its approval (for example, a change in dosing interval) may have an impact on the substitutability of already approved generic versions of that product that were rated by the Agency as therapeutically equivalent to the listed product. When such changes in the listed drug product are considered by the Agency to have a significant impact on therapeutic equivalence, the Agency will change the therapeutic equivalence ratings for other versions of the drug product unless the manufacturers of those other versions of the product provide additional information to assure equivalence under the changed conditions. Pending receipt of the additional data, the Agency may add a note to Section 1.8, or, in rare cases, may even change the therapeutic equivalence rating.

In some cases (e.g., Isolyte® S w/ Dextrose 5% in Plastic Container and Plasma-Lyte® 148 and Dextrose 5% in Plastic Container), closely related products are listed as containing the same active ingredients, but in

somewhat different amounts. In determining which of these products are pharmaceutically equivalent, generally the Agency has considered products to be pharmaceutically equivalent with labeled strengths of an ingredient that do not vary by more than 1%.

Different salts, esters or other noncovalent derivatives (such as a complex, chelate, or clathrate) of the same active moiety are regarded as different active ingredients. For the purpose of this publication, products containing such different active ingredients are considered pharmaceutical alternatives and, thus, not therapeutically equivalent. Anhydrous and hydrated entities, as well as different polymorphs, are considered to be the same active ingredient and are expected to meet the same standards for identity to be considered pharmaceutical equivalents and therapeutic equivalents.

The codes in this book are not intended to preclude health care professionals from converting pharmaceutically different concentrations into pharmaceutical equivalents using accepted professional practice.

Where package size variations have therapeutic implications, products so packaged have not been considered pharmaceutically equivalent. For example, some oral contraceptives are supplied in 21-tablet and 28-tablet packets; the 28-tablet packets contain 7 placebo or iron tablets. These two packaging configurations are not regarded as pharmaceutically equivalent; thus, they are not designated as therapeutically equivalent.

Preservatives and other inactive ingredients may differ among some therapeutically equivalent drug products. These differences do not affect FDA's evaluation of therapeutic equivalence except in cases where these components may influence bioequivalence or routes of administration.

The specific sub-codes for those drugs evaluated as therapeutically equivalent and the policies underlying these sub-codes follow:

AA Products in conventional dosage forms not presenting bioequivalence problems

Multisource drug products coded as **AA** contain active ingredients and are in dosage forms that are not regarded as presenting either actual or potential bioequivalence problems or drug quality or standards issues. However, all oral dosage forms must, nonetheless, meet an appropriate *in vitro* bioequivalence standard that is acceptable to the Agency in order to be approved.

AB, AB1, AB2, AB3... Products meeting necessary bioequivalence requirements

Multisource drug products listed under the same heading (i.e., identical active ingredients(s), dosage form, and route(s) of administration) and having the same strength (see Section 1.2, *Therapeutic Equivalence-Related Terms, Strength)* generally will be coded **AB** if data and information are submitted demonstrating bioequivalence.

In certain instances, a number is added to the end of the **AB** code to make a three character code (i.e., **AB1, AB2, AB3, etc.**). Three-character codes generally are assigned only in situations when more than one reference listed drug of the same strength has been designated under the same heading. Two or more reference listed drugs are generally selected only when there are at least two potential reference listed drug products that are not identified as bioequivalent to each other. If a study is submitted that demonstrates bioequivalence to a specific listed drug product, the generic product will be given the same three-character code

as the reference listed drug it was compared against. For example, Adalat® CC and Procardia XL®, extended-release tablets, are listed under the active ingredient nifedipine. These drug products, listed under the same heading, are not bioequivalent to each other. Adalat® CC and Procardia XL® have been assigned ratings of **AB1** and **AB2**, respectively. Generic drug products deemed by FDA to be bioequivalent to Adalat® CC and Procardia XL® have been approved. As a result, the generic drug products bioequivalent to Adalat® CC have been assigned a rating of **AB1** and those bioequivalent to Procardia XL® have been assigned a rating of **AB2**. (The assignment of an **AB1** or **AB2** rating to a specific product does not imply product preference.) Even though drug products of distributors and/or repackagers are not included in the Orange Book, they are considered therapeutically equivalent to the applicant's drug product if the applicant's drug product is rated either with an **AB** or three-character code or is single source in the Orange Book. Drugs coded as **AB** under a heading are considered therapeutically equivalent only to other drugs coded as **AB** under that heading. Drugs coded with a three-character code under a heading are considered therapeutically equivalent only to other drugs coded with the same three-character code under that heading.

AN Solutions and powders for aerosolization

Uncertainty regarding the therapeutic equivalence of aerosolized products arises primarily because of differences in the drug delivery system. Solutions and powders intended for aerosolization that are marketed for use in general-use delivery systems are considered to be pharmaceutically and therapeutically equivalent and are coded **AN**. Those products that are compatible only with a specific delivery system or those products that are packaged in and with a specific delivery system are coded **BN**, unless they have met an appropriate bioequivalence standard and are otherwise determined to be therapeutically equivalent. Solutions or suspensions in a specific delivery system will be coded **AN** if the bioequivalence standard is based upon *in vitro* methodology, if bioequivalence needs to be demonstrated by *in vivo* methodology then the drug products will be coded **AB**.

AO Injectable oil solutions

The absorption of drugs in injectable (parenteral) oil solutions may vary substantially with the type of oil employed as a vehicle and the concentration of the active ingredient. Injectable oil solutions are therefore considered to be pharmaceutically and therapeutically equivalent only when the active ingredient, its concentration, and the type of oil used as a vehicle are all identical.

AP Injectable aqueous solutions and, in certain instances, intravenous non-aqueous solutions

It should be noted that even though injectable (parenteral) products under a specific listing may be evaluated as therapeutically equivalent, there may be important differences among the products in the general category, Injectable; Injection. For example, historically some injectable products that are rated therapeutically equivalent are labeled for different routes of administration. In addition, some products evaluated as therapeutically equivalent may have different preservatives or no preservatives at all. Injectable products available as dry powders for reconstitution, concentrated sterile solutions for dilution, or sterile solutions ready for injection are pharmaceutical alternative drug

products. They are not rated as therapeutically equivalent (AP) to each other even if these pharmaceutical alternative drug products are designed to produce the same concentration prior to injection and are similarly labeled. Consistent with accepted professional practice, it is the responsibility of the prescriber, dispenser, or individual administering the product to be familiar with a product's labeling to assure that it is given only by the route(s) of administration stated in the labeling.

Certain commonly used large volume intravenous products in glass containers are not included in the Orange Book (e.g., dextrose injection 5%, dextrose injection 10%, sodium chloride injection 0.9%) since these products are on the market without FDA approval and the FDA has not published conditions for marketing such parenteral products under approved NDAs. When packaged in plastic containers, however, FDA regulations require approved applications prior to marketing. Approval then depends on, among other things, the extent of the available safety data involving the specific plastic component of the product. All large volume parenteral products are manufactured under similar standards, regardless of whether they are packaged in glass or plastic. Thus, FDA has no reason to believe that the packaging container of large volume parenteral drug products that are pharmaceutically equivalent would have any effect on their therapeutic equivalence.

Consistent with the definition of strength included in Section 1.2, *Therapeutic Equivalence-Related Terms,* the strength of parenteral drug products generally is identified by both the total drug content and the concentration of drug substance in a container approved by FDA.[8] In the past, the strength of liquid parenteral drug products in the Orange Book has not been fully displayed. Rather, the strength of liquid parenteral drug products in the Orange Book has been displayed in terms of concentration, expressed as xmg/mL. Generally, the amount of dry powder or lyophilized powder in a container is identified as the strength, expressed as xmg/vial.

After the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which amended the FD&C Act, it became evident that the format of the Orange Book with respect to parenteral solutions should be changed to reflect that each strength of a drug is considered to be a separate listed drug. The Orange Book now displays the strength of all new approvals of parenteral solutions. Previously, we would have displayed only the concentration of an approved parenteral solution, e.g. 50mg/mL. If this application had a 20 mL and 60 mL container approved, we would now display two product strengths, listing both total drug content and concentration of drug substance in the relevant approved container, e.g. 1gm/20mL (50mg/mL) and 3gm/60mL (50mg/mL).

AT Topical products

There are a variety of topical dosage forms available for dermatologic, ophthalmic, otic, rectal, and vaginal administration, including creams, gels, lotions, oils, ointments, pastes, solutions, sprays and suppositories. Even though different topical dosage forms may contain the same active ingredient and potency, these dosage forms are not considered pharmaceutically equivalent. Therefore, they are not considered therapeutically equivalent. All solutions and DESI drug products

8 The strengths of certain parenteral drug products, including contrast agents, may be expressed as a percentage.

containing the same active ingredient in the same topical dosage form for which a waiver of *in vivo* bioequivalence has been granted and for which chemistry and manufacturing processes are adequate to demonstrate bioequivalence, are considered therapeutically equivalent and coded **AT**. Pharmaceutically equivalent topical products that raise questions of bioequivalence, including all post-1962 non-solution topical drug products, are coded **AB** when supported by adequate bioequivalence data, and **BT** in the absence of such data.

"B" CODES

Drug products that FDA, at this time, considers not to be therapeutically equivalent to other pharmaceutically equivalent products.

"**B**" products, for which actual or potential bioequivalence problems have not been resolved by adequate evidence of bioequivalence, often have a problem with specific dosage forms rather than with the active ingredients. Drug products designated with a "**B**" code fall under one of three main policies:

(1) the drug products contain active ingredients or are manufactured in dosage forms that have been identified by the Agency as having documented bioequivalence problems or a significant potential for such problems and for which no adequate studies demonstrating bioequivalence have been submitted to FDA; or

(2) the quality standards are inadequate or FDA has an insufficient basis to determine therapeutic equivalence; or

(3) the drug products are under regulatory review.

The specific coding definitions and policies for the "**B**" sub-codes are as follows:

B* Drug products requiring further FDA investigation and review to determine therapeutic equivalence

The code **B*** is assigned to products previously assigned an **A** or **B** code when FDA receives new information that raises a significant question regarding therapeutic equivalence that can be resolved only through further Agency investigation and/or review of data and information submitted by the applicant. The **B*** code signifies that the Agency will take no position regarding the therapeutic equivalence of the product until the Agency completes its investigation and review.

BC Extended-release dosage forms (capsules, injectables and tablets)

Extended-release tablets are formulated in such a manner as to make the contained drug substance available over an extended period of time following ingestion.

Although bioavailability studies have been conducted on these dosage forms, they may be subject to bioavailability differences, primarily because applicants developing extended-release products for the same active ingredient rarely employ the same formulation approach. FDA, therefore, does not consider different extended-release dosage forms containing the same active ingredient in equal strength to be therapeutically equivalent unless equivalence between individual products

in both rate and extent has been specifically demonstrated through appropriate bioequivalence studies. Extended-release products for which such bioequivalence data have not been submitted are coded **BC**, while those for which such data are available have been coded **AB**.

BD Active ingredients and dosage forms with documented bioequivalence problems

The **BD** code denotes products containing active ingredients with known bioequivalence problems and for which adequate studies have not been submitted to FDA demonstrating bioequivalence. Where studies showing bioequivalence have been submitted, the product has been coded **AB**.

BE Delayed-release oral dosage forms

Where the drug may be destroyed or inactivated by the gastric juice or where it may irritate the gastric mucosa, the use of “enteric” coatings is indicated. Such coatings are intended to delay the release of the medication until the tablet has passed through the stomach. Drug products in delayed-release dosage forms containing the same active ingredients are subject to significant differences in absorption. Unless otherwise specifically noted, the Agency considers different delayed-release products containing the same active ingredients as presenting a potential bioequivalence problem and codes these products **BE** in the absence of *in vivo* studies showing bioequivalence. If adequate *in vivo* studies have demonstrated the bioequivalence of specific delayed-release products, such products are coded **AB**.

BN Products in aerosol-nebulizer drug delivery systems

This code applies to drug solutions or powders that are marketed only as a component of, or as compatible with, a specific drug delivery system. There may, for example, be significant differences in the dose of drug and particle size delivered by different products of this type. Therefore, the Agency does not consider different metered aerosol dosage forms containing the same active ingredient(s) in equal strengths to be therapeutically equivalent unless the drug products meet an appropriate bioequivalence standard; such products are coded **AB**.

BP Active ingredients and dosage forms with potential bioequivalence problems

FDA's bioequivalence regulations (21 CFR 320.33) contain criteria and procedures for determining whether a specific active ingredient in a specific dosage form has a potential for causing a bioequivalence problem. It is FDA's policy to consider an ingredient meeting these criteria as having a potential bioequivalence problem even in the absence of positive data demonstrating inequivalence. Pharmaceutically equivalent products containing these ingredients in oral dosage forms are coded **BP** until adequate bioequivalence data are submitted, after which such products are coded **AB**. Injectable suspensions containing an active ingredient suspended in an aqueous or oleaginous vehicle have also been coded **BP**. Injectable suspensions are subject to bioequivalence problems because differences in particle size, polymorphic structure of the suspended active ingredient, or the suspension formulation can significantly affect the rate of release and absorption. FDA does not consider pharmaceutical equivalents of these products bioequivalent without adequate evidence of bioequivalence; such products would be coded **AB**.

BR Suppositories or enemas that deliver drugs for systemic absorption

The absorption of active ingredients from suppositories or enemas that are intended to have a systemic effect (as distinct from suppositories administered for local effect) can vary significantly from product to product. Therefore, FDA considers pharmaceutically equivalent systemic suppositories or enemas bioequivalent only if *in vivo* evidence of bioequivalence is available. In those cases where *in vivo* evidence is available, the products are coded **AB**. If such evidence is not available, the products are coded **BR**.

BS Products having drug standard deficiencies

If the drug standards for an active ingredient in a particular dosage form are found by FDA to be deficient so as to prevent an FDA evaluation of either pharmaceutical or therapeutic equivalence, all drug products containing that active ingredient in that dosage form are coded **BS**. For example, if the standards permit a wide variation in pharmacologically active components of the active ingredient such that pharmaceutical equivalence is in question, all products containing that active ingredient in that dosage form are coded **BS**.

BT Topical products with bioequivalence issues

This code applies mainly to post-1962 dermatologic, ophthalmic, otic, rectal, and vaginal products for topical administration, including creams, ointments, gels, lotions, pastes, and sprays, as well as suppositories not intended for systemic drug absorption. Topical products evaluated as having acceptable clinical performance, but that are not bioequivalent to other pharmaceutically equivalent products or that lack sufficient evidence of bioequivalence, will be coded **BT**.

BX Drug products for which the data are insufficient to determine therapeutic equivalence

The code **BX** is assigned to specific drug products for which the data that have been reviewed by the Agency are insufficient to determine therapeutic equivalence under the policies stated in this document. In these situations, the drug products are presumed to be therapeutically inequivalent until the Agency has determined that there is adequate information to make a full evaluation of therapeutic equivalence.

1.8 Description of Certain Special Situations

Certain drugs listed in the Orange Book present special situations that merit further discussion. The following are descriptions of certain examples of those special situations:

Amino Acid and Protein Hydrolysate Injections. These products differ in the amount and kinds of amino acids they contain and, therefore, are not considered pharmaceutical equivalents. For this reason, these products are not considered therapeutically equivalent. At the same time, the Agency believes that it is appropriate to point out that where nitrogen balance is the sole therapeutic objective and individual amino acid content is not a consideration, pharmaceutical alternatives with the same total amount of nitrogen content may be considered therapeutically equivalent.

Gaviscon®. Gaviscon® is an OTC product that has been marketed since September 1970. The active ingredients in this product, aluminum hydroxide and magnesium trisilicate, were reviewed by the Agency's OTC Antacid Panel and were considered to be safe and effective ingredients (Category I) by that Panel. However, the tablet failed to pass the antacid test that is required of all antacid products. The Agency, therefore, placed the tablet in Category III for lack of effectiveness. A full NDA with clinical studies was submitted by Marion Laboratories, Inc., and approved by FDA on December 9, 1983. Gaviscon®'s activity in treating reflux acidity is made possible by the physical-chemical properties of the inactive ingredients, sodium bicarbonate and alginic acid. Therefore, *all ANDAs that cite Gaviscon® tablets as the reference listed drug must contain the inactive ingredients sodium bicarbonate and alginic acid.* A full NDA will be required to support the effectiveness of the drug product if different inactive ingredients are to be substituted for sodium bicarbonate or alginic acid or if different proportions of these ingredients are to be used.

Levothyroxine Sodium. Because there are multiple reference listed drugs of levothyroxine sodium tablets and some reference listed drugs' sponsors have conducted studies to establish their drugs' therapeutic equivalence to other reference listed drugs, FDA has determined that its usual practice of assigning two or three character TE codes may be potentially confusing and inadequate for these drug products. Accordingly, FDA provides the following explanation and chart of therapeutic equivalence evaluations for levothyroxine sodium tablet drug products.

Levothyroxine Sodium (Mylan ANDA 076187), Levoxyl (King Pharms NDA 021301), Synthroid (Abbvie NDA 021402), and Levo-T (CEDIPROF NDA 021342) tablets have been determined to be therapeutically equivalent to corresponding strengths of Unithroid (Jerome Stevens NDA 021210) tablets.

Levo-T (CEDIPROF NDA 021342), Levothyroxine Sodium (Mylan ANDA 076187), and Unithroid (Jerome Stevens NDA 021210) tablets have been determined to be therapeutically equivalent to corresponding strengths of Synthroid (Abbvie NDA 021402) tablets.

Levo-T (CEDIPROF NDA 021342), Unithroid (Jerome Stevens NDA 021210), and Levothyroxine Sodium (Mylan ANDA 076187) tablets have been determined to be therapeutically equivalent to corresponding strengths of Levoxyl (King Pharms NDA 021301) tablets.

Levothyroxine Sodium (Mylan ANDA 076187) tablets have been determined to be therapeutically equivalent to corresponding strengths of Thyro-Tabs (Lloyd NDA 021116) tablets.[9]

The chart outlines TE codes for all 0.025 mg products in the active section of the Orange Book. Other product strengths may be similar. Therapeutic equivalence has been established between products that have the same AB+number TE code. More than one TE code may apply to some products. One

9 Lloyd's Thyro-Tabs tablets (NDA 021116) (previously known as Levothroid) is currently listed in the Discontinued Drug Product List section of the Orange Book and Mylan's levothyroxine product (ANDA 076187) has been selected as the reference standard for ANDA applicants to use to establish bioequivalence to Thyro-Tabs. If an ANDA that uses Mylan's levothyroxine product as its reference standard is approved, the ANDA will receive an AB4 rating. The ANDA applicant also may obtain an AB rating for its product to the other reference listed drugs (i.e., Unithroid, Synthroid, and Levoxyl) by submitting supplements that demonstrate that the generic product is bioequivalent to these other reference listed drugs and satisfies all other therapeutic equivalence criteria with respect to these reference listed drugs. See Letter from Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, FDA to Teri Nataline, Principal Consultant, Lachman Consultant Services, Inc., Docket No. FDA-2015-P-0403 (May 27, 2016).

common TE code indicates therapeutic equivalence between products.

Trade Name	Applicant	Strength	TE Code	Appl No	Product No
UNITHROID	STEVENS J	0.025MG	AB1	021210	001
LEVOTHYROXINE SODIUM	MYLAN	0.025MG	AB1	076187	001
LEVOXYL	KING PHARMS	0.025MG	AB1	021301	001
SYNTHROID	ABBVIE	0.025MG	AB1	021402	001
LEVO-T	CEDIPROF INC	0.025MG	AB1	021342	001
SYNTHROID	ABBVIE	0.025MG	AB2	021402	001
LEVOTHYROXINE SODIUM	MYLAN	0.025MG	AB2	076187	001
LEVO-T	CEDIPROF INC	0.025MG	AB2	021342	001
UNITHROID	STEVENS J	0.025MG	AB2	021210	001
LEVOXYL	KING PHARMS	0.025MG	AB3	021301	001
LEVO-T	CEDIPROF INC	0.025MG	AB3	021342	001
UNITHROID	STEVENS J	0.025MG	AB3	021210	001
LEVOTHYROXINE SODIUM	MYLAN	0.025MG	AB3	076187	001
THYRO-TABS	LLOYD	0.025MG	N/A[10]	021116	001
LEVOTHYROXINE SODIUM	MYLAN	0.025MG	AB4	076187	001

Patent Certification(s) and Reference Standard for ANDAs Duplicating a Drug Product Approved in a Petitioned ANDA. To submit an ANDA for a generic drug that is not the same as its reference listed drug because it has one different active ingredient (in a fixed combination drug product), or has a different route of administration, dosage form, or strength than that of the reference listed drug, an applicant first must obtain permission from FDA through what is known as a suitability petition pursuant to section 505(j)(2)(C) of the FD&C Act. A petitioned ANDA relies on the reference listed drug described in the suitability petition. An ANDA for a drug that is the same as a drug product approved in a petitioned ANDA should utilize the drug product approved in the petitioned ANDA as a reference standard. However, the reference listed drug for any such ANDA is generally the listed drug referenced in the approved suitability petition. The ANDA must include appropriate patent certification(s) and an exclusivity statement with respect to the reference listed drug that served as the basis for the approved suitability petition.[11] (This concept also generally applies to an ANDA applicant that utilizes a reference standard that is not a reference listed drug, as such an application must include appropriate patent certification(s) and an exclusivity statement with respect to the reference listed drug.)

Waived exclusivity. If an NDA submitted under Section 505(b) of the FD&C

10 Thyro-Tabs is in the Discontinued Drug Product List and therefore no longer is assigned a TE code.

11 If after approval of a suitability petition and before approval of an ANDA submitted pursuant to the approved petition, a drug product is approved in an NDA for the change described in the petition, the suitability petition and the listed drug identified in the petition can no longer be the basis of submission for such ANDA. Under these circumstances, an applicant seeking approval for a drug product with the change approved in the suitability petition must submit a new ANDA that identifies the drug product approved under such NDA as the RLD and comply with applicable regulatory requirements. See 21 CFR 314.93(f)(2).

Act qualifies for exclusivity under the FD&C Act, the exclusivity is generally listed in the Patent and Exclusivity Section of the Orange Book. If a drug product has received this exclusivity, the FDA will not accept for review and/or will not approve a 505(b)(2) application or an ANDA under Section 505(j) of the FD&C Act, as applicable, in accordance with the relevant exclusivity. If the listed drug is also protected by one or more patents, the approval date for the ANDA or 505(b)(2) application will be determined based on an analysis of the applicant's patent certification(s) or statement(s) for each relevant patent and the effect of relevant exclusivity listed in the Orange Book. However, the holder of the NDA may waive its exclusivity as to any or all ANDAs and 505(b)(2) applications that might otherwise be blocked by such exclusivity. If an NDA sponsor waives its right to the exclusivity protection, qualified ANDAs or 505(b)(2) applications may be accepted for review and/or approved, as applicable, pursuant to the NDA holder's exclusivity being waived. An NDA for which the holder has waived its exclusivity as to all ANDAs and 505(b)(2) applications will be coded with a "W" in the Patent and Exclusivity Section of the Orange Book. The applicant whose product might otherwise be blocked by this exclusivity should indicate in the exclusivity statement in its application that the holder of the listed drug has waived its exclusivity.

1.9 Therapeutic Equivalence Code Change for a Category of Multisource Drug Products

The Agency will use the following procedures when, in response to a petition or on its own initiative, it is considering a change in the therapeutic equivalence code for approved multisource drug products. Such changes will generally occur when the Agency becomes aware of new scientific information affecting the therapeutic equivalence of an entire category of multisource drug products in the Orange Book (e.g., information concerning the active ingredient or the dosage form), rather than information concerning a single drug product within the category. These procedures will be used when a change in therapeutic equivalence code is under consideration for all drug products found in the Prescription Drug Product List under a specific drug entity and dosage form. The change may be from the code signifying that the drug does not present a bioequivalence problem (e.g., **AA**) to a code signifying an actual or potential bioequivalence problem (e.g., **BP**), or vice versa. This procedure does not apply to a change of a particular product code (e.g., a change from **BP** to **AB** or from **AB** to **BX**).

Before making a change in a therapeutic equivalence code for an entire category of multisource drug products as described above, the Agency will announce in the *Introduction* to the Cumulative Supplement that it is considering the change and will invite comments. Comments, along with scientific data, may be sent to the Director, Office of Bioequivalence, Office of Generic Drugs, Center for Drug Evaluation and Research, HFD-650, 7620 Standish Place, Rockville, MD 20855.

The comment period will generally be 60 days in length, and the closing date for comments will be listed in the description of the proposed change for each drug entity.

The most useful type of scientific data submitted to support comments is an *in vivo* bioavailability/bioequivalence study conducted on batches of the subject drug products. Comments including scientific data from an *in vivo* bioavailability/bioequivalence study should present a full description of the analytical procedures and equipment used, a validation of the analytical methodology, including the standard curve, a description of the method of calculating results, and a description of the pharmacokinetic and statistical models used in analyzing the data. Anecdotal or testimonial information is the least useful to the Agency, and submission of comments based on such

information is discouraged. However, when there is supporting published or unpublished scientific literature, copies should be submitted with comments.

1.10 Change of the Therapeutic Equivalence Evaluation for a Single Product

The procedure described in Section 1.9 does not apply to a change in a single drug product code. For example, a change in a single drug product's code from **BP** to **AB** as a result of the submission of an acceptable bioequivalence study ordinarily will not be the subject of notice and comment in the Cumulative Supplement. Likewise, a change in a single drug product's code from **AB** to **BX** (e.g., as a result of new information raising a significant question as to bioequivalence) does not require notice and comment. The Agency's responsibility to provide the public with the Agency's most current information related to therapeutic equivalence may require a change in a drug product's code prior to any formal notice and opportunity for the applicant to be heard. The publication in the *Federal Register* of a proposal to withdraw approval of a drug product will ordinarily result in a change in a product's code from **AB** to **BX** if this action has not already been taken.

We recognize that certain drug products approved in 505(b)(2) applications may not have therapeutic equivalence codes, and that FDA may undertake therapeutic equivalence evaluations with respect to such drug products. A person seeking to have a therapeutic equivalence rating for a drug product approved in a 505(b)(2) application may petition the Agency through the citizen petition procedure (see 21 CFR 10.25(a) and 21 CFR 10.30).

1.11 Discontinued Section

Those drug products in the discontinued section of the Orange Book (Discontinued Drug Product List) for which a determination has been made that the products were not withdrawn for safety or effectiveness reasons have been annotated with a footnote following the product strength: “**Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons**”. The determinations listed in Orange Book are only reflective of determinations made since 1995 and published in the Federal Register. The identification of these drug products in the Discontinued Drug Product List should avoid the submission of multiple citizen petitions requesting a determination for the same drug product.

Generally, approved products are added to the Discontinued Drug Product List when the applicant notifies the Orange Book staff of the products’ not-marketed status. Products may also be added to the Discontinued Drug Product List if annual reports or other submissions to the Agency indicate the product is not being marketed or as a result of other Agency administrative actions.[12] Changes to the Orange Book are not affected by the drug registration and listing requirements of Section 510 of the FD&C Act.

1.12 Changes to the Orange Book

Every effort is made to ensure the Annual Edition is current and accurate. Applicants are requested to inform the FDA Orange Book Staff of any changes or corrections, including any change in a product’s marketing status that would result in the product being moved to the Discontinued Drug

12 See, e.g., Section 506I(d) of the FD&C Act.

Product List. FDA notes that under Section 506I(a) of the FD&C Act, applicants must notify the Agency in writing 180 days prior to withdrawing a drug product from sale, or if 180 days is not practicable, not later than the date of withdrawal from sale. Furthermore, Section 506I(b) of the FD&C Act requires that applicants notify the Agency in writing within 180 days of approval of a drug product if such drug product will not be available for sale within 180 days of approval. A request to include a newly approved product in the Discontinued Drug Product List, rather than parts 1, 2 or 3 of the Orange Book (as discussed in Section 1.1), must be submitted to the Orange Book staff by the end of the month in which the product is approved to ensure that the product is not included in the "active" portions of the next published Orange Book update.

In addition, FDA Orange Book Staff generally will act on requests to change a proprietary name for a listed drug only after approval of a supplement for the relevant change in proprietary name. To the extent that conventions for describing product identification information (i.e., active ingredients, dosage forms, routes of administration, product names, applicants, strengths) evolve over time, the Agency generally does not intend to revise such information for drug products already included in the Orange Book, but rather intends to apply the change prospectively to drug products added to the Orange Book.

You can contact the Orange Book Staff by email at orangebook@fda.hhs.gov. If you do not have access to email, you can contact the Orange Book Staff by mail at:

FDA/CDER Orange Book Staff
Office of Generic Drug Policy
Office of Generic Drugs
7620 Standish Place
Rockville, MD 20855-2773

1.13 Availability of the Edition

Commencing with the 25th edition, the Annual Edition and current monthly Cumulative Supplement are available in a Portable Document Format (PDF) at the Orange Book home page by clicking on Publications. The PDF annual format duplicates previous paper versions except for the Orphan Products Designations and Approvals List. An annual subscription of the PDF format may be obtained from the U.S. Government Publishing Office, 866-512-1800.

2. HOW TO USE THE DRUG PRODUCT LISTS

2.1 Key Sections for Using the Drug Product Lists

This publication contains illustrations, along with Drug Product Lists, indices, and lists of abbreviations and terms which facilitate their use.

Illustrations. The annotated *Drug Product Illustration*, see Section 2.2, and the *Therapeutic Equivalence Evaluations Illustration*, see Section 2.3, are offered to provide further clarification. These depict the format found in the Prescription Drug Product List (the only list in which therapeutic equivalence evaluation codes are displayed).

Drug Product Lists. The Prescription and OTC Drug Product Lists, arranged alphabetically by active ingredient(s), contain product identification information (active ingredients, dosage forms, routes of administration, product names, applicants, strengths) for single and multiple ingredient drug products. Also shown are the application number and drug product number (FDA internal computer data use only) and approval dates for those drug products approved on or after January 1, 1982. The application number preceded by “N” is a New Drug Application (NDA or commonly the innovator). The application number preceded by an “A” is an Abbreviated New Drug Application (ANDA or commonly the generic).

The Discontinued Drug Product List, arranged alphabetically by active ingredient(s), contains product identification information (dosage form, product name, strength, and application number).

If a prescription drug product is available from more than one source (multisource), a therapeutic equivalence code will appear in front of the applicant's name. If a product is therapeutically equivalent to one or more products or to an appropriate reference, it will be designated with a code beginning with "**A**" and the entry will be underlined and printed in bold font for emphasis.

Active ingredient headings for multiple ingredient (combination) drug products are arranged alphabetically. For purposes of this publication, this alphabetical sort takes precedence over United States Pharmacopeia official monograph order (i.e., Reserpine, Hydralazine Hydrochloride, Hydrochlorothiazide). For example, product information labeled as Reserpine, Hydrochlorothiazide and Hydralazine Hydrochloride appears under the active ingredient heading *Hydralazine Hydrochloride; Hydrochlorothiazide; Reserpine*. A cross-reference to the product information (for prescription and OTC products) appears for each additional active ingredient in the product. For combination drug products, the ingredient strengths are separated by semicolons and appear in the same relative sequence as the ingredients in the heading. Available strengths of the dosage form from an applicant appear on separate lines.

To use the Drug Product Lists, determine by alphabetical order the ingredient under which the product information is listed, using the Product Name Index, if necessary. Then, find the ingredient in the applicable Drug Product List. Proceed to the dosage form and route of administration and compare products within that ingredient heading only. Therapeutic equivalence or inequivalence for prescription products is determined on the basis of the therapeutic equivalence codes provided within that specific dosage form and route heading. The OTC Drug Product List, Discontinued Drug Product List, and

Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research List have their data arranged similarly.

The Discontinued Drug Product List contains approved products that have never been marketed, have been discontinued from marketing and we have not determined that they were withdrawn for safety or effectiveness reasons, are for military use, or have had their approvals withdrawn for other than safety or efficacy reasons subsequent to being discontinued from marketing. All products having a "@" in the December Cumulative Supplement of the previous Edition List have been added to the Discontinued Drug Product List appearing in this Edition. In addition, approved drug products that are not in the commercial distribution channel e.g., approved drug products in applications for export only are also listed in the Discontinued Drug Product List.

Product Name Index *(Prescription and OTC Drug Product Lists)*. This is an index of drug products by trade name or established name of the active ingredient, if no trade name exists. The second term of each entry indicates the active ingredient name under which product information can be found in the appropriate Drug Product List. For those drug products with multiple active ingredients, only the first active ingredient (in alphabetical order) will appear. OTC products are so designated.

Product Name Index Listed by Applicant *(Prescription and OTC Drug Product Lists*). This is an index that cross-references applicants to drug products. The bolded and underlined entry represents the applicant name abbreviation used in this publication. Each complete applicant name that is represented by the abbreviated name is marked with an asterisk (*). Listed under each complete applicant name is the first alphabetically arranged ingredient under which product information can be found in the appropriate Drug Product List. OTC products are so designated. To use the Drug Product Lists, determine by alphabetical order the ingredient under which the product information is listed, using the Product Name Index, if appropriate.

Uniform Terms. To improve readability, uniform terms are used to designate dosage forms, routes of administration, and abbreviations used to express strengths. These terms are listed in Appendix C. In some cases, the terms used may differ from those used in product labels and other labeling.

2.2 DRUG PRODUCT ILLUSTRATION

SINGLE INGREDIENT

ACTIVE INGREDIENT → MEPERIDINE HYDROCHLORIDE

DOSAGE FORM; ROUTE OF ADMINISTRATION → INJECTABLE;INJECTION

TRADE OR GENERIC NAMES → **HEXANON**

REFERENCE LISTED DRUG* (+)
REFERENCE STANDARD * (!)

AP	**+!** PAGE PHARMA	**25MG/ML**	**N013111**	**001**	AUG 22, 1983
AP	**+!**	**50MG/ML**	**N013111**	**002**	AUG 22, 1983
AP	**+!**	**75MG/ML**	**N013111**	**003**	AUG 22, 1983
AP	**+!**	**100MG/ML**	**N013111**	**004**	JAN 04, 1989

MEPERIDINE HCL

THERAPEUTIC EQUIVALENCE (TE) CODE FOR MULTISOURCE PRODUCT →

AP	GREENBERG PHARM	**25MG/ML**	**A064890**	001	FEB 29, 1987
AP		**50MG/ML**	**A064890**	002	FEB 29, 1987
AP		**75MG/ML**	**A064890**	003	FEB 29, 1987
AP		**100MG/ML**	**A064890**	004	MAR 08, 1992

SINGLE SOURCE PRODUCT (NO TE CODE)

!	TIMOKIM LLC	10MG/ML	A099225	001	DEC 12, 1995
AP	JOHNSON MED	**25MG/ML**	**A099226**	**001**	NOV 27, 1993
!	KENDRA PHARM	150MG/ML	A079444	001	OCT 31, 1999

APPLICANT →

AVAILABLE STRENGTH(S) OF A PRODUCT →

APPLICATION NUMBER AND PRODUCT NUMBER →
PRODUCT NUMBER IS FOR FDA INTERNAL COMPUTER DATA USE ONLY →

APPROVAL DATE →

*NOTE: REFERENCE LISTED DRUG AND REFERENCE STANDARD ARE DISCUSSED IN THE PREFACE SECTION 1.4

MULTIPLE INGREDIENTS WITH PRODUCT INFORMATION

ALPHABETICALLY SORTED BY
ACTIVE INGREDIENT → HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE

PRODUCT INFORMATION →

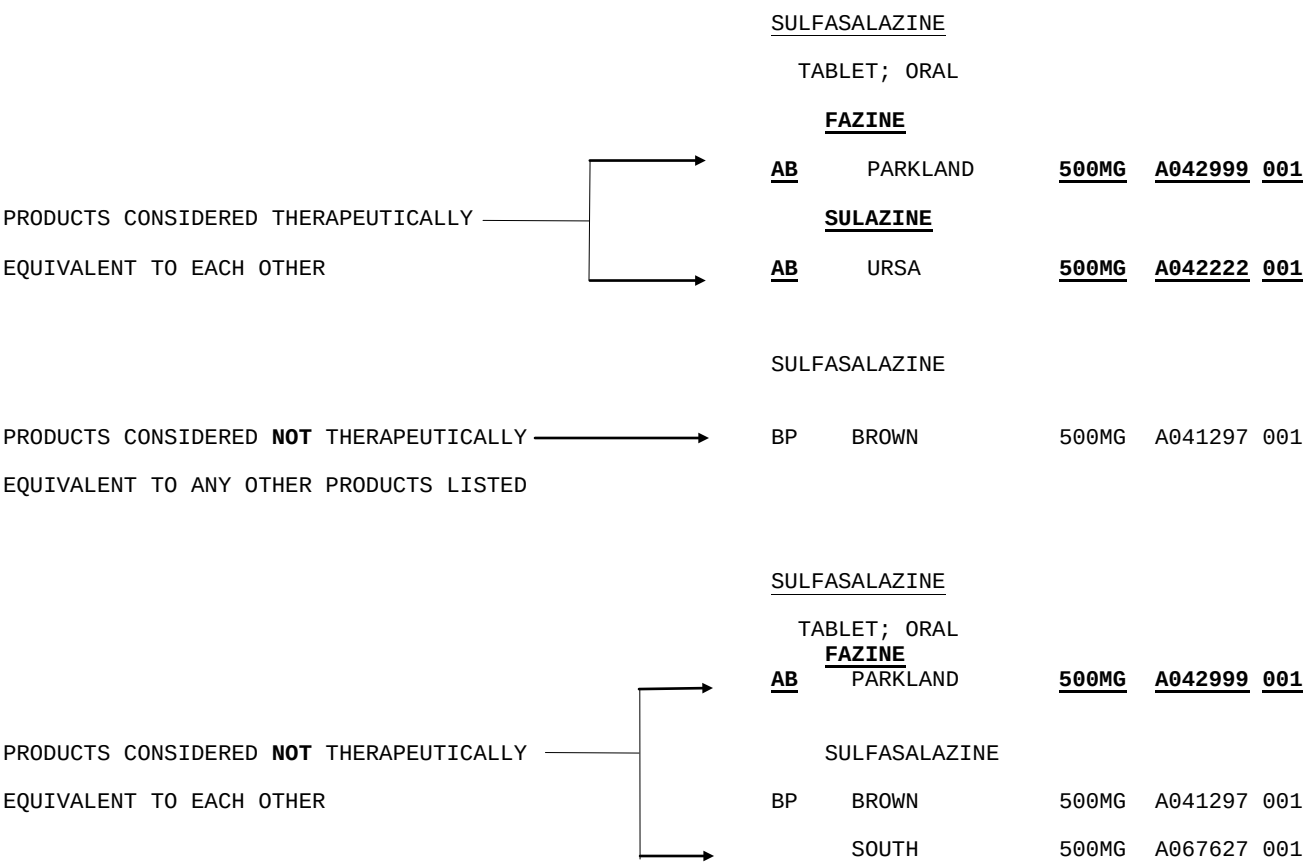
TABLET;ORAL
HYDROCHLOROTHIAZIDE, RESERPINE AND HYDRALAZINE HCL

REINWALD LABS	25MG;15MG;0.1MG	A069808	001	JAN 18, 1982

THIS EXAMPLE IS FOR PURPOSE OF ILLUSTRATION ONLY. IT DOES NOT REPRESENT ACTUAL PRODUCTS FROM THE PRESCRIPTION DRUG PRODUCT LIST.

2.3 THERAPEUTIC EQUIVALENCE EVALUATIONS ILLUSTRATION

DRUG PRODUCTS CODED **AB** (OR ANY CODE BEGINNING WITH AN **"A"**) UNDER AN INGREDIENT AND DOSAGE FORM HEADING ARE CONSIDERED THERAPEUTICALLY EQUIVALENT ONLY TO OTHER PRODUCTS CODED **AB** (OR ANY CODE BEGINNING WITH AN **A")** AND **NOT** TO THOSE CODED **BP** (OR ANY CODE BEGINNING WITH **"B"**) AND ANY PRODUCTS NOT LISTED. DRUG PRODUCTS CODED **BP** (OR ANY CODE BEGINNING WITH A **"B"**) ARE **NOT** CONSIDERED THERAPEUTICALLY EQUIVALENT TO ANY OTHER PRODUCT. FOR A COMPLETE EXPLANATION OF THE **TE** CODES REFER TO SECTION 1.7 OF THE *INTRODUCTION.*



NOTE: BOLD FONT AND UNDERLINING DENOTES MULTISOURCE PRODUCTS WHICH ARE CONSIDERED THERAPEUTICALLY EQUIVALENT.

THIS EXAMPLE IS FOR PURPOSES OF ILLUSTRATION ONLY. IT DOES NOT REPRESENT ACTUAL PRODUCTS FROM THE PRESCRIPTION DRUG PRODUCT LIST.

AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL

TABLET;ORAL

TRIBENZOR

AB	+	DAIICHI SANKYO	EQ 5MG BASE;12.5MG;20MG	N200175	001	Jul 23, 2010
AB	+		EQ 5MG BASE;12.5MG;40MG	N200175	002	Jul 23, 2010
AB	+		EQ 5MG BASE;25MG;40MG	N200175	003	Jul 23, 2010
AB	+		EQ 10MG BASE;12.5MG;40MG	N200175	004	Jul 23, 2010
AB	+!		EQ 10MG BASE;25MG;40MG	N200175	005	Jul 23, 2010

AMLODIPINE BESYLATE; HYDROCHLOROTHIAZIDE; VALSARTAN

TABLET;ORAL

AMLODIPINE BESYLATE, VALSARTAN AND HYDROCHLOROTHIAZIDE

AB		AUROBINDO PHARMA LTD	5MG;12.5MG;160MG	A206180	001	Dec 19, 2017
AB			5MG;25MG;160MG	A206180	002	Dec 19, 2017
AB			10MG;12.5MG;160MG	A206180	003	Dec 19, 2017
AB			10MG;25MG;160MG	A206180	004	Dec 19, 2017
AB			10MG;25MG;320MG	A206180	005	Dec 19, 2017
AB		LUPIN LTD	5MG;12.5MG;160MG	A200797	001	Jun 03, 2015
AB			5MG;25MG;160MG	A200797	002	Jun 03, 2015
AB			10MG;12.5MG;160MG	A200797	003	Jun 03, 2015
AB			10MG;25MG;160MG	A200797	004	Jun 03, 2015
AB			10MG;25MG;320MG	A200797	005	Jun 03, 2015
AB		PAR PHARM	5MG;12.5MG;160MG	A201087	001	Jun 01, 2015
AB			5MG;25MG;160MG	A201087	002	Jun 01, 2015
AB			10MG;12.5MG;160MG	A201087	003	Jun 01, 2015
AB			10MG;25MG;160MG	A201087	004	Jun 01, 2015
AB			10MG;25MG;320MG	A201087	005	Jun 01, 2015
AB		TEVA PHARMS	5MG;12.5MG;160MG	A200435	001	Sep 25, 2012
AB			5MG;25MG;160MG	A200435	002	Sep 25, 2012
AB			10MG;12.5MG;160MG	A200435	005	Sep 25, 2012
AB			10MG;25MG;160MG	A200435	003	Sep 25, 2012
AB			10MG;25MG;320MG	A200435	004	Sep 25, 2012
AB		TORRENT PHARMS LTD	5MG;12.5MG;160MG	A201593	001	Jun 03, 2015
AB			5MG;25MG;160MG	A201593	002	Jun 03, 2015
AB			10MG;12.5MG;160MG	A201593	003	Jun 03, 2015
AB			10MG;25MG;160MG	A201593	004	Jun 03, 2015
AB			10MG;25MG;320MG	A201593	005	Jun 03, 2015

EXFORGE HCT

AB	+	NOVARTIS	5MG;12.5MG;160MG	N022314	001	Apr 30, 2009
AB	+		5MG;25MG;160MG	N022314	002	Apr 30, 2009
AB	+		10MG;12.5MG;160MG	N022314	003	Apr 30, 2009
AB	+		10MG;25MG;160MG	N022314	004	Apr 30, 2009
AB	+!		10MG;25MG;320MG	N022314	005	Apr 30, 2009

AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL

TABLET;ORAL

AMLODIPINE AND OLMESARTAN MEDOXOMIL

AB		AJANTA PHARMA LTD	EQ 5MG BASE;20MG	A207216	001	Oct 28, 2016
AB			EQ 5MG BASE;40MG	A207216	002	Oct 28, 2016
AB			EQ 10MG BASE;20MG	A207216	003	Oct 28, 2016
AB			EQ 10MG BASE;40MG	A207216	004	Oct 28, 2016
AB		ALEMBIC PHARMS LTD	EQ 5MG BASE;20MG	A207073	001	Jul 17, 2017
AB			EQ 5MG BASE;40MG	A207073	002	Jul 17, 2017
AB			EQ 10MG BASE;20MG	A207073	003	Jul 17, 2017
AB			EQ 10MG BASE;40MG	A207073	004	Jul 17, 2017
AB		ALKEM LABS LTD	EQ 5MG BASE;20MG	A209042	001	Aug 14, 2017
AB			EQ 5MG BASE;40MG	A209042	002	Aug 14, 2017
AB			EQ 10MG BASE;20MG	A209042	003	Aug 14, 2017
AB			EQ 10MG BASE;40MG	A209042	004	Aug 14, 2017
AB		AUROBINDO PHARMA LTD	EQ 5MG BASE;20MG	A206906	001	May 15, 2017
AB			EQ 5MG BASE;40MG	A206906	002	May 15, 2017
AB			EQ 10MG BASE;20MG	A206906	003	May 15, 2017
AB			EQ 10MG BASE;40MG	A206906	004	May 15, 2017
AB		GLENMARK PHARMS LTD	EQ 5MG BASE;20MG	A207807	001	Jul 05, 2017
AB			EQ 5MG BASE;40MG	A207807	002	Jul 05, 2017
AB			EQ 10MG BASE;20MG	A207807	003	Jul 05, 2017
AB			EQ 10MG BASE;40MG	A207807	004	Jul 05, 2017
AB		JUBILANT GENERICS	EQ 5MG BASE;20MG	A207450	001	May 15, 2017
AB			EQ 5MG BASE;40MG	A207450	002	May 15, 2017
AB			EQ 10MG BASE;20MG	A207450	003	May 15, 2017
AB			EQ 10MG BASE;40MG	A207450	004	May 15, 2017
AB		MACLEODS PHARMS LTD	EQ 5MG BASE;20MG	A206884	001	Oct 26, 2016

AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL

TABLET;ORAL

AMLODIPINE AND OLMESARTAN MEDOXOMIL

AB			EQ 5MG BASE;40MG	A206884	003	Oct 26, 2016
AB			EQ 10MG BASE;20MG	A206884	002	Oct 26, 2016
AB			EQ 10MG BASE;40MG	A206884	004	Oct 26, 2016
AB		MICRO LABS	EQ 5MG BASE;20MG	A207435	001	Nov 02, 2017
AB			EQ 5MG BASE;40MG	A207435	002	Nov 02, 2017
AB			EQ 10MG BASE;20MG	A207435	003	Nov 02, 2017
AB			EQ 10MG BASE;40MG	A207435	004	Nov 02, 2017
AB		TEVA PHARMS USA	EQ 5MG BASE;20MG	A091154	001	Oct 26, 2016
AB			EQ 5MG BASE;40MG	A091154	002	Oct 26, 2016
AB			EQ 10MG BASE;20MG	A091154	003	Oct 26, 2016
AB			EQ 10MG BASE;40MG	A091154	004	Oct 26, 2016
AB		TORRENT PHARMS LTD	EQ 5MG BASE;20MG	A202933	001	Nov 25, 2016
AB			EQ 5MG BASE;40MG	A202933	002	Nov 25, 2016
AB			EQ 10MG BASE;20MG	A202933	003	Nov 25, 2016
AB			EQ 10MG BASE;40MG	A202933	004	Nov 25, 2016
AB		ZYDUS PHARMS USA INC	EQ 5MG BASE;20MG	A207771	001	Sep 22, 2017
AB			EQ 5MG BASE;40MG	A207771	002	Sep 22, 2017
AB			EQ 10MG BASE;20MG	A207771	003	Sep 22, 2017
AB			EQ 10MG BASE;40MG	A207771	004	Sep 22, 2017

AZOR

AB	+	DAIICHI SANKYO	EQ 5MG BASE;20MG	N022100	001	Sep 26, 2007
AB	+		EQ 5MG BASE;40MG	N022100	002	Sep 26, 2007
AB	+		EQ 10MG BASE;20MG	N022100	003	Sep 26, 2007
AB	+!		EQ 10MG BASE;40MG	N022100	004	Sep 26, 2007

AMLODIPINE BESYLATE; PERINDOPRIL ARGININE

TABLET;ORAL

PRESTALIA

	+	MARINA BIOTECH	EQ 2.5MG BASE;3.5MG	N205003	001	Jan 21, 2015
	+		EQ 5MG BASE;7MG	N205003	002	Jan 21, 2015
	+!		EQ 10MG BASE;14MG	N205003	003	Jan 21, 2015

AMLODIPINE BESYLATE; TELMISARTAN

TABLET;ORAL

TELMISARTAN AND AMLODIPINE

AB		ALEMBIC PHARMS LTD	EQ 5MG BASE;40MG	A205234	001	Nov 17, 2016
AB			EQ 5MG BASE;80MG	A205234	003	Nov 17, 2016
AB			EQ 10MG BASE;40MG	A205234	002	Nov 17, 2016
AB			EQ 10MG BASE;80MG	A205234	004	Nov 17, 2016
AB		LUPIN LTD	EQ 5MG BASE;40MG	A201586	001	Jan 08, 2014
AB			EQ 5MG BASE;80MG	A201586	003	Jan 08, 2014
AB			EQ 10MG BASE;40MG	A201586	002	Jan 08, 2014
AB			EQ 10MG BASE;80MG	A201586	004	Jan 08, 2014
AB		MYLAN PHARMS INC	EQ 5MG BASE;40MG	A202516	001	Aug 26, 2014
AB			EQ 5MG BASE;80MG	A202516	003	Aug 26, 2014
AB			EQ 10MG BASE;40MG	A202516	002	Aug 26, 2014
AB			EQ 10MG BASE;80MG	A202516	004	Aug 26, 2014
AB		TORRENT PHARMS LTD	EQ 5MG BASE;40MG	A202517	001	Jan 08, 2014
AB			EQ 5MG BASE;80MG	A202517	003	Jan 08, 2014
AB			EQ 10MG BASE;40MG	A202517	002	Jan 08, 2014
AB			EQ 10MG BASE;80MG	A202517	004	Jan 08, 2014

TWYNSTA

AB	+	BOEHRINGER INGELHEIM	EQ 5MG BASE;40MG	N022401	001	Oct 16, 2009
AB	+		EQ 5MG BASE;80MG	N022401	003	Oct 16, 2009
AB	+		EQ 10MG BASE;40MG	N022401	002	Oct 16, 2009
AB	+!		EQ 10MG BASE;80MG	N022401	004	Oct 16, 2009

AMLODIPINE BESYLATE; VALSARTAN

TABLET;ORAL

AMLODIPINE BESYLATE AND VALSARTAN

AB		ALEMBIC PHARMS LTD	EQ 5MG BASE;160MG	A202713	001	Apr 03, 2015
AB			EQ 5MG BASE;320MG	A202713	003	Apr 03, 2015
AB			EQ 10MG BASE;160MG	A202713	002	Apr 03, 2015
AB			EQ 10MG BASE;320MG	A202713	004	Apr 03, 2015
AB		AUROBINDO PHARMA LTD	EQ 5MG BASE;160MG	A206512	001	Apr 22, 2016
AB			EQ 5MG BASE;320MG	A206512	002	Apr 22, 2016
AB			EQ 10MG BASE;160MG	A206512	003	Apr 22, 2016
AB			EQ 10MG BASE;320MG	A206512	004	Apr 22, 2016

AMLODIPINE BESYLATE; VALSARTAN

TABLET;ORAL

AMLODIPINE BESYLATE AND VALSARTAN

AB		INVAGEN PHARMS	EQ 5MG BASE;160MG	A205137	001	Sep 16, 2016
AB			EQ 5MG BASE;320MG	A205137	003	Sep 16, 2016
AB			EQ 10MG BASE;160MG	A205137	002	Sep 16, 2016
AB			EQ 10MG BASE;320MG	A205137	004	Sep 16, 2016
AB		LUPIN	EQ 5MG BASE;160MG	A090245	001	Mar 30, 2015
AB			EQ 5MG BASE;320MG	A090245	003	Mar 30, 2015
AB			EQ 10MG BASE;160MG	A090245	002	Mar 30, 2015
AB			EQ 10MG BASE;320MG	A090245	004	Mar 30, 2015
AB		MYLAN PHARMS INC	EQ 5MG BASE;160MG	A090483	001	Mar 30, 2015
AB			EQ 5MG BASE;320MG	A090483	003	Mar 30, 2015
AB			EQ 10MG BASE;160MG	A090483	002	Mar 30, 2015
AB			EQ 10MG BASE;320MG	A090483	004	Mar 30, 2015
AB		NOVEL LABS INC	EQ 5MG BASE;160MG	A202829	001	Mar 30, 2015
AB			EQ 5MG BASE;320MG	A202829	003	Mar 30, 2015
AB			EQ 10MG BASE;160MG	A202829	002	Mar 30, 2015
AB			EQ 10MG BASE;320MG	A202829	004	Mar 30, 2015
AB		PAR PHARM INC	EQ 5MG BASE;160MG	A090011	001	Mar 28, 2013
AB			EQ 5MG BASE;320MG	A090011	003	Mar 28, 2013
AB			EQ 10MG BASE;160MG	A090011	002	Mar 28, 2013
AB			EQ 10MG BASE;320MG	A090011	004	Mar 28, 2013
AB		TEVA PHARMS USA	EQ 5MG BASE;160MG	A091235	001	Mar 30, 2015
AB			EQ 5MG BASE;320MG	A091235	003	Mar 30, 2015
AB			EQ 10MG BASE;160MG	A091235	002	Mar 30, 2015
AB			EQ 10MG BASE;320MG	A091235	004	Mar 30, 2015
AB		TORRENT PHARMS LTD	EQ 5MG BASE;160MG	A202377	001	Mar 30, 2015
AB			EQ 5MG BASE;320MG	A202377	002	Mar 30, 2015
AB			EQ 10MG BASE;160MG	A202377	003	Mar 30, 2015
AB			EQ 10MG BASE;320MG	A202377	004	Mar 30, 2015

EXFORGE

AB	+	NOVARTIS	EQ 5MG BASE;160MG	N021990	002	Jun 20, 2007
AB	+		EQ 5MG BASE;320MG	N021990	004	Jun 20, 2007
AB	+!		EQ 10MG BASE;160MG	N021990	003	Jun 20, 2007
AB	+!		EQ 10MG BASE;320MG	N021990	005	Jun 20, 2007

AMMONIA N-13

INJECTABLE;INTRAVENOUS

AMMONIA N 13

AP		3D IMAGING DRUG	30mCi-300mCi/8ML (3.75-37.5mCi/ML)	A203779	001	Oct 19, 2015
AP		BIOMEDCL RES FDN	48.75mCi-487.5mCi/13ML (3.75-37.5mCi/ML)	A204352	001	May 01, 2015
AP		BRIGHAM WOMENS HOSP	30mCi-300mCi/8ML (3.75-37.5mCi/ML)	A203783	001	Oct 30, 2014
AP		CARDINAL HEALTH 414	30mCi-300mCi/8ML (3.75-37.5mCi/ML)	A203700	001	Feb 25, 2013
AP	+!	FEINSTEIN	30mCi-300mCi/8ML (3.75-37.5mCi/ML)	N022119	001	Aug 23, 2007
AP		GEN HOSP	30mCi-300mCi/8ML (3.75-37.5mCi/ML)	A207025	001	Feb 03, 2016
AP		GLOBAL ISOTOPES LLC	30mCi-300mCi/8ML (3.75-37.5mCi/ML)	A204465	001	Oct 23, 2014
AP		IBA MOLECULAR N AM	18.8mCi-188mCi/5ML (3.75-37.5mCi/ML)	A204667	001	Apr 22, 2015
AP		JOHNS HOPKINS UNIV	30mCi-300mCi/8ML (3.75-37.5mCi/ML)	A204514	001	Aug 19, 2014
AP		KREITCHMAN PET CTR	30mCi-300mCi/8ML (3.75-37.5mCi/ML)	A203938	001	Dec 09, 2013
AP		MCPRF	30mCi-300mCi/8ML (3.75-37.5mCi/ML)	A203321	001	Feb 25, 2013
AP		MIDWEST MEDCL	30mCi-300mCi/8ML (3.75-37.5mCi/ML)	A204457	001	Nov 18, 2015
AP		MIPS CRF	30mCi-300mCi/8ML (3.75-37.5mCi/ML)	A204535	001	Nov 20, 2014
AP		PETNET	30mCi-300mCi (3.75-37.5mCi/ML)	A204510	001	Nov 02, 2015
AP		SPECTRON MRC LLC	30mCi-300mCi/8ML (3.75-37.5mCi/ML)	A204455	001	Apr 23, 2015
AP		UCLA BIOMEDICAL	30mCi-300mCi/8ML (3.75-37.5mCi/ML)	A203812	001	Jun 27, 2013
AP		UCSF RODIOPHARM	30mCi-300mCi/8ML (3.75-37.5mCi/ML)	A204496	001	Mar 28, 2014
AP		UNIV TX MD ANDERSON	30mCi-300mCi/8ML (3.75-37.5mCi/ML)	A203933	001	Jun 27, 2014
AP		WA UNIV SCH MED	30mCi-300mCi/8ML (3.75-37.5mCi/ML)	A204506	001	Feb 07, 2014
		ESSENTIAL ISOTOPES	3.75-260mCi/ML	A205687	001	Dec 17, 2015
		HOUSTON CYCLOTRON	3.75-260mCi/ML	A203543	001	Dec 14, 2012
		NCM USA BRONX LLC	3.75-260mCi/mL	A204515	001	Feb 04, 2015
		PRECISION NUCLEAR	3.75-260mCi/ML	A204547	001	Aug 14, 2015
		SHERTECH LABS LLC	3.75-260mCi/ML	A204366	001	Sep 19, 2014
		WI MEDCL CYCLOTRON	3.75-260mCi/ML	A204356	001	Dec 18, 2014

AMMONIUM CHLORIDE

INJECTABLE;INJECTION

AMMONIUM CHLORIDE IN PLASTIC CONTAINER

	!	HOSPIRA	5MEQ/ML	A088366	001	Jun 13, 1984

HYDROCHLOROTHIAZIDE; VALSARTAN							
TABLET;ORAL							
DIOVAN HCT							
AB	+	NOVARTIS	**12.5MG;80MG**	**N020818**	**001**	Mar 06, 1998
AB	+		**12.5MG;160MG**	**N020818**	**002**	Mar 06, 1998
AB	+		**12.5MG;320MG**	**N020818**	**004**	Apr 28, 2006
AB	+		**25MG;160MG**	**N020818**	**003**	Jan 17, 2002
AB	+!		**25MG;320MG**	**N020818**	**005**	Apr 28, 2006
VALSARTAN AND HYDROCHLOROTHIAZIDE							
AB		ALEMBIC PHARMS LTD	**12.5MG;80MG**	**A201662**	**001**	Mar 21, 2013
AB			**12.5MG;160MG**	**A201662**	**002**	Mar 21, 2013
AB			**12.5MG;320MG**	**A201662**	**003**	Mar 21, 2013
AB			**25MG;160MG**	**A201662**	**004**	Mar 21, 2013
AB			**25MG;320MG**	**A201662**	**005**	Mar 21, 2013
AB		APOTEX INC	**12.5MG;80MG**	**A203026**	**001**	Mar 21, 2013
AB			**12.5MG;160MG**	**A203026**	**002**	Mar 21, 2013
AB			**12.5MG;320MG**	**A203026**	**003**	Mar 21, 2013
AB			**25MG;160MG**	**A203026**	**004**	Mar 21, 2013
AB			**25MG;320MG**	**A203026**	**005**	Mar 21, 2013
AB		AUROBINDO PHARMA LTD	**12.5MG;80MG**	**A202519**	**001**	Mar 21, 2013
AB			**12.5MG;160MG**	**A202519**	**002**	Mar 21, 2013
AB			**12.5MG;320MG**	**A202519**	**003**	Mar 21, 2013
AB			**25MG;160MG**	**A202519**	**004**	Mar 21, 2013
AB			**25MG;320MG**	**A202519**	**005**	Mar 21, 2013
AB		LUPIN LTD	**12.5MG;80MG**	**A078946**	**003**	Mar 21, 2013
AB			**12.5MG;160MG**	**A078946**	**004**	Mar 21, 2013
AB			**12.5MG;320MG**	**A078946**	**001**	Mar 21, 2013
AB			**25MG;160MG**	**A078946**	**005**	Mar 21, 2013
AB			**25MG;320MG**	**A078946**	**002**	Mar 21, 2013
AB		MACLEODS PHARMS LTD	**12.5MG;80MG**	**A203145**	**001**	Apr 19, 2013
AB			**12.5MG;160MG**	**A203145**	**002**	Apr 19, 2013
AB			**12.5MG;320MG**	**A203145**	**003**	Apr 19, 2013
AB			**25MG;160MG**	**A203145**	**004**	Apr 19, 2013
AB			**25MG;320MG**	**A203145**	**005**	Apr 19, 2013
AB		MYLAN PHARMS INC	**12.5MG;80MG**	**A078020**	**001**	Sep 21, 2012
AB			**12.5MG;160MG**	**A078020**	**002**	Sep 21, 2012
AB			**12.5MG;320MG**	**A078020**	**004**	Sep 21, 2012
AB			**25MG;160MG**	**A078020**	**003**	Sep 21, 2012
AB			**25MG;320MG**	**A078020**	**005**	Sep 21, 2012
AB		PRINSTON INC	**12.5MG;80MG**	**A206083**	**001**	Feb 08, 2016
AB			**12.5MG;160MG**	**A206083**	**002**	Feb 08, 2016
AB			**12.5MG;320MG**	**A206083**	**003**	Feb 08, 2016
AB			**25MG;160MG**	**A206083**	**004**	Feb 08, 2016
AB			**25MG;320MG**	**A206083**	**005**	Feb 08, 2016
AB		WATSON LABS TEVA	**12.5MG;80MG**	**A091519**	**001**	Mar 21, 2013
AB			**12.5MG;160MG**	**A091519**	**002**	Mar 21, 2013
AB			**12.5MG;320MG**	**A091519**	**003**	Mar 21, 2013
AB			**25MG;160MG**	**A091519**	**004**	Mar 21, 2013
AB			**25MG;320MG**	**A091519**	**005**	Mar 21, 2013
HYDROCODONE BITARTRATE							
CAPSULE, EXTENDED RELEASE;ORAL							
ZOHYDRO ER							
	+!	PERNIX IRELAND PAIN	10MG	N202880	001	Oct 25, 2013
	+		15MG	N202880	002	Oct 25, 2013
	+		20MG	N202880	003	Oct 25, 2013
	+		30MG	N202880	004	Oct 25, 2013
	+		40MG	N202880	005	Oct 25, 2013
	+		50MG	N202880	006	Oct 25, 2013
TABLET, EXTENDED RELEASE;ORAL							
HYSINGLA							
	+!	PURDUE PHARMA LP	20MG	N206627	001	Nov 20, 2014
	+		30MG	N206627	002	Nov 20, 2014
	+		40MG	N206627	003	Nov 20, 2014
	+		60MG	N206627	004	Nov 20, 2014
	+		80MG	N206627	005	Nov 20, 2014
	+		100MG	N206627	006	Nov 20, 2014
	+		120MG	N206627	007	Nov 20, 2014
VANTRELA ER							
	+	TEVA BRANDED PHARM	15MG	N207975	001	Jan 17, 2017
	+		30MG	N207975	002	Jan 17, 2017
	+		45MG	N207975	003	Jan 17, 2017

VALPROATE SODIUM							
INJECTABLE;INJECTION							
DEPACON							
AP	**+!**	ABBVIE	**EQ 100MG BASE/ML**	**N020593**	**001**	Dec 30, 1996
VALPROATE SODIUM							
AP		ATHENEX INC	**EQ 100MG BASE/ML**	**A076295**	**001**	Nov 14, 2002
AP		FRESENIUS KABI USA	**EQ 100MG BASE/ML**	**A076539**	**001**	Jun 26, 2003
AP		HIKMA FARMACEUTICA	**EQ 100MG BASE/ML**	**A078523**	**001**	Feb 17, 2010
VALPROIC ACID							
CAPSULE;ORAL							
DEPAKENE							
AB	**+!**	ABBVIE	**250MG**	**N018081**	**001**	
VALPROIC ACID							
AB		BIONPHARMA INC	**250MG**	**A073484**	**001**	Jun 29, 1993
AB		CATALENT	**250MG**	**A073229**	**001**	Oct 29, 1991
AB		SUN PHARM INDS LTD	**250MG**	**A091037**	**001**	Feb 22, 2013
SYRUP;ORAL							
DEPAKENE							
AA	**+!**	ABBVIE	**250MG/5ML**	**N018082**	**001**	
VALPROIC ACID							
AA		ANI PHARMS INC	**250MG/5ML**	**A073178**	**001**	Aug 25, 1992
AA		ECI PHARMS LLC	**250MG/5ML**	**A090517**	**001**	May 28, 2010
AA		HIGH TECH PHARMA	**250MG/5ML**	**A074060**	**001**	Jan 13, 1995
AA		PHARM ASSOC	**250MG/5ML**	**A075379**	**001**	Dec 15, 2000
AA		VINTAGE	**250MG/5ML**	**A077960**	**001**	Oct 13, 2006
AA		VISTAPHARM	**250MG/5ML**	**A075782**	**001**	Dec 22, 2000
AA		WOCKHARDT BIO AG	**250MG/5ML**	**A070868**	**001**	Jul 01, 1986
VALRUBICIN							
SOLUTION;INTRAVESICAL							
VALSTAR PRESERVATIVE FREE							
	+!	ENDO PHARM	40MG/ML	N020892	001	Sep 25, 1998
VALSARTAN							
SOLUTION;ORAL							
PREXXARTAN							
	+!	CARMEL BIOSCIENCES	20MG/5ML	N209139	001	Dec 19, 2017
	+!		80MG/20ML	N209139	002	Dec 19, 2017
TABLET;ORAL							
DIOVAN							
AB	**+**	NOVARTIS	**40MG**	**N021283**	**004**	Aug 14, 2002
AB	**+**		**80MG**	**N021283**	**001**	Jul 18, 2001
AB	**+**		**160MG**	**N021283**	**002**	Jul 18, 2001
AB	**+!**		**320MG**	**N021283**	**003**	Jul 18, 2001
VALSARTAN							
AB		ALEMBIC PHARMS LTD	**40MG**	**A091367**	**001**	Jan 05, 2015
AB			**80MG**	**A091367**	**002**	Jan 05, 2015
AB			**160MG**	**A091367**	**003**	Jan 05, 2015
AB			**320MG**	**A091367**	**004**	Jan 05, 2015
AB		AMNEAL PHARMS	**40MG**	**A204011**	**001**	Jan 11, 2016
AB			**80MG**	**A204011**	**002**	Jan 11, 2016
AB			**160MG**	**A204011**	**003**	Jan 11, 2016
AB			**320MG**	**A204011**	**004**	Jan 11, 2016
AB		AUROBINDO PHARMA LTD	**40MG**	**A202223**	**001**	Jan 05, 2015
AB			**80MG**	**A202223**	**002**	Jan 05, 2015
AB			**160MG**	**A202223**	**003**	Jan 05, 2015
AB			**320MG**	**A202223**	**004**	Jan 05, 2015
AB		HETERO LABS LTD V	**40MG**	**A203311**	**001**	Jan 05, 2015
AB			**80MG**	**A203311**	**002**	Jan 05, 2015
AB			**160MG**	**A203311**	**003**	Jan 05, 2015
AB			**320MG**	**A203311**	**004**	Jan 05, 2015
AB		IVAX PHARMS	**40MG**	**A077530**	**001**	Jan 04, 2016
AB			**80MG**	**A077530**	**002**	Jan 04, 2016
AB			**160MG**	**A077530**	**003**	Jan 04, 2016
AB			**320MG**	**A077530**	**004**	Jan 04, 2016
AB		JUBILANT GENERICS	**40MG**	**A203536**	**001**	Jan 05, 2015
AB			**80MG**	**A203536**	**002**	Jan 05, 2015
AB			**160MG**	**A203536**	**003**	Jan 05, 2015
AB			**320MG**	**A203536**	**004**	Jan 05, 2015
AB		LUPIN LTD	**40MG**	**A201677**	**001**	Jan 05, 2015
AB			**80MG**	**A201677**	**002**	Jan 05, 2015
AB			**160MG**	**A201677**	**003**	Jan 05, 2015

VALSARTAN

TABLET;ORAL

VALSARTAN

AB			320MG	A201677	004	Jan 05, 2015
AB		MACLEODS PHARMS LTD	40MG	A202696	001	Sep 16, 2016
AB			80MG	A202696	002	Sep 16, 2016
AB			160MG	A202696	003	Sep 16, 2016
AB			320MG	A202696	004	Sep 16, 2016
AB		MYLAN PHARMS INC	40MG	A090866	001	Jan 05, 2015
AB			80MG	A090866	002	Jan 05, 2015
AB			160MG	A090866	003	Jan 05, 2015
AB			320MG	A090866	004	Jan 05, 2015
AB		OHM LABS INC	40MG	A077492	001	Jun 26, 2014
AB			80MG	A077492	002	Jun 26, 2014
AB			160MG	A077492	003	Jun 26, 2014
AB			320MG	A077492	004	Jun 26, 2014
AB		PRINSTON INC	40MG	A204821	001	Jun 09, 2015
AB			80MG	A204821	002	Jun 09, 2015
AB			160MG	A204821	003	Jun 09, 2015
AB			320MG	A204821	004	Jun 09, 2015
AB		TORRENT PHARMS LTD	40MG	A202728	001	Jan 05, 2015
AB			80MG	A202728	002	Jan 05, 2015
AB			160MG	A202728	003	Jan 05, 2015
AB			320MG	A202728	004	Jan 05, 2015
AB		WATSON LABS INC	40MG	A090642	001	Jan 05, 2015
AB			80MG	A090642	002	Jan 05, 2015
AB			160MG	A090642	003	Jan 05, 2015
AB			320MG	A090642	004	Jan 05, 2015

VANCOMYCIN HYDROCHLORIDE

CAPSULE;ORAL

VANCOCIN HYDROCHLORIDE

AB	+	ANI PHARMS INC	EQ 125MG BASE	N050606	001	Apr 15, 1986
AB	+!		EQ 250MG BASE	N050606	002	Apr 15, 1986

VANCOMYCIN HYDROCHLORIDE

AB		AKORN	EQ 125MG BASE	A065478	001	Apr 09, 2012
AB			EQ 250MG BASE	A065478	002	Apr 09, 2012
AB		FRESENIUS KABI USA	EQ 125MG BASE	A065453	001	Jun 18, 2012
AB			EQ 250MG BASE	A065453	002	Jun 18, 2012
AB		LUPIN LTD	EQ 125MG BASE	A090439	001	Jan 28, 2015
AB			EQ 250MG BASE	A090439	002	Jan 28, 2015
AB		STRIDES PHARMA	EQ 125MG BASE	A065490	001	Apr 09, 2012
AB			EQ 250MG BASE	A065490	002	Apr 09, 2012
AB		WATSON LABS	EQ 125MG BASE	A065510	001	Apr 09, 2012
AB			EQ 250MG BASE	A065510	002	Apr 09, 2012

INJECTABLE;INJECTION

VANCOMYCIN HYDROCHLORIDE

AP		AUROBINDO PHARMA LTD	EQ 500MG BASE/VIAL	A205780	001	Mar 31, 2016
AP			EQ 1GM BASE/VIAL	A205780	002	Mar 31, 2016
AP			EQ 5GM BASE/VIAL	A205779	001	Mar 29, 2016
AP			EQ 10GM BASE/VIAL	A205779	002	Mar 29, 2016
AP		CFT PHARMS LLC	EQ 5GM BASE/VIAL	A204125	001	Dec 28, 2015
AP			EQ 10GM BASE/VIAL	A204125	002	Dec 28, 2015
AP			EQ 500MG BASE/VIAL	A204107	001	Dec 28, 2015
AP			EQ 1GM BASE/VIAL	A204107	002	Dec 28, 2015
AP		EMCURE PHARMS LTD	EQ 500MG BASE/VIAL	A202275	001	Oct 31, 2013
AP			EQ 1GM BASE/VIAL	A202275	002	Oct 31, 2013
AP			EQ 10GM BASE/VIAL	A202464	001	Oct 09, 2013
AP			EQ 5GM BASE/VIAL	A202274	001	Oct 31, 2013
AP	!	FRESENIUS KABI USA	EQ 500MG BASE/VIAL	A062663	001	Mar 17, 1987
AP			EQ 750MG BASE/VIAL	A062663	005	Aug 17, 2016
AP	!		EQ 1GM BASE/VIAL	A062663	002	Jul 31, 1987
AP	!		EQ 5GM BASE/VIAL	A062663	003	Jun 03, 1988
AP	!		EQ 10GM BASE/VIAL	A062663	004	Nov 28, 1997
AP		GLAND PHARMA LTD	EQ 500MG BASE/VIAL	A205694	001	Jan 21, 2016
AP			EQ 1GM BASE/VIAL	A205694	002	Jan 21, 2016
AP	!	HOSPIRA	EQ 500MG BASE/VIAL	A062911	001	Aug 04, 1988
AP	!		EQ 500MG BASE/VIAL	A062931	001	Oct 29, 1992
AP	!		EQ 750MG BASE/VIAL	A062912	002	Jan 07, 2009
AP	!		EQ 750MG BASE/VIAL	A062933	002	May 27, 2009
AP	!		EQ 1GM BASE/VIAL	A062912	001	Aug 04, 1988
AP	!		EQ 1GM BASE/VIAL	A062933	001	Oct 29, 1992